DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0165]

Draft Guidance for Industry on the Current Good Manufacturing Practices for Medical Gases; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period on the draft guidance for industry entitled ''Current Good Manufacturing Practice for Medical Gases.'' The agency issued this draft guidance in the **Federal Register** of May 6, 2003 (68 FR 24005). The initial comment period closes on September 3, 2003. To provide interested persons additional time to review the draft guidance and submit comments, the agency has decided to extend the comment period.

DATES: Written comments on the draft guidance may be submitted by November 3, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http:/*

/www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Duane S. Sylvia, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–9040, e-mail: *Sylviad@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is extending the comment period on the draft guidance for industry entitled ''Current Good Manufacturing Practice for Medical Gases.'' This draft guidance is intended to provide recommendations on how to comply with current good manufacturing practice (CGMP) regulations for manufacturing, filling, transfilling, cascading, and transferring compressed and cryogenic medical gases. The guidance should help manufacturers and distributors comply with the CGMP requirements to ensure the identity, strength, quality, and purity of medical gases.

The agency issued this draft guidance on May 6, 2003. The initial comment period closes on September 3, 2003, but at the request of the medical gas industry, the agency has decided to extend the comment period for an additional 60 days, until November 3, 2003.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance . Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received

comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of this draft guidance for industry are available on the Internet at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/ohrms/dockets/default.htm*, and *http://www.fda.gov/cder/dmpq/gases.htm*.

Dated: August 20, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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